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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,721

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Ralf Himmelreich

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

12/30/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

Office Action Summary	Application No. 10/577,721	Applicant(s) HIMMELREICH ET AL.	
	Examiner TERESA E. STRZELECKA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1 and 4-22 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1 and 4-22 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. This office action is in response to an amendment filed November 22, 2011. Claims 1 and 4-22 were previously pending. Applicant did not amend any claims.
2. Applicant's arguments are insufficient to overcome the previously presented rejections for reasons given in the "Response to Arguments" below.

Response to Arguments

3. Applicant's arguments filed November 22, 2011 have been fully considered but they are not persuasive. Only arguments regarding the rejection of claims 1, 5-10, 14 and 16-18 under 35 U.S.C. 102(b) over Smith et al. are addressed, as arguments concerning other rejections rely on the arguments presented regarding the 102(b) rejection.

Applicant argues the following:

- i) "Claim 1 recites that the target DNA binds directly to a porous matrix consisting of a material based on silica or a silica coated material. The Office Action appears to equate the porous silica-based matrix of the present invention with the solid matrix plus ion exchange material disclosed by Smith et al. The term "silica-based matrix" as used in the present claims is a term of art indicating a solid matrix consisting of materials based on silica, such as glass, for example, which is distinct from an ion exchange matrix as taught by Smith et al. In fact, Smith et al. teach that a "silica based matrix" component like that used in the present invention is used in combination with an ion exchange matrix. See col. 9:32 - 10:30. Thus, Smith et al. provides evidence that the term "silica based matrix" as used herein does not include materials that are not based on silica, such as the ligands taught by Smith et al. Thus, the prior art cited in the Office Action actually teaches that the claimed invention does not include non-silica based materials in the solid matrix to which the nucleic acids bind.

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Smith teaches use of an ion exchange matrix attached to a porous or nonporous silica-based matrix support, and teaches that the target nucleic acid attaches to the ion exchange matrix, not the silica based support, establishing an indirect binding of the DNA to the support matrix. Thus, Smith does not teach or suggest the claimed invention.”

ii) “The Office Action finds that the present claims do not require that the DNA binds directly to the SiO groups of the silica based materials and therefore, makes a correlation between Applicants' claims to direct binding to the solid porous silica based matrix and Smith's use of ion exchange matrices attached to the solid (optionally silica based) support matrix. This correlation has no basis in fact. The fact that the present claims do not specify the molecular binding responsible for the direct binding to the porous silica-based matrix is of no consequence since the claims require that the binding be directly to the silica-based solid matrix and the specification makes clear that the silica-based matrix does not contain non-silica based components. Recitation of how direct binding is accomplished is not required for patentability. The fact is, the present inventors' have discovered that there is no need to modify the surface of a silica-based or silica coated porous matrix to include an ion exchange matrix, for example, in order to capture the filtered DNA in the absence of a chaotropic agent and/or alcohol.

Smith et al. expressly teaches the addition of functional groups to the surface of the solid matrix, *e.g.*, multiple ion exchange matrices attached to a silica based matrix, to capture filtered DNA, thereby indirectly binding the DNA to the solid matrix *via* non-silica-based materials. Thus, Smith et al. does not teach all of the elements of the present claims and does not suggest the claimed invention.”

First, there is no definition in the case that specifies that “silica-based matrix” refers to a material which does not contain any other functional groups. There is no requirement anywhere in the specification that the “silica based matrix” is a material that does not contain any additional functional groups rather than SiO groups. Therefore, examiner's interpretation of the term as a silica matrix with additional functional groups is not unreasonable, since such matrix is silica-based, i.e. the starting material is silica. Since Smith et al. teach silica matrix with attached ion exchange groups, they expressly teach silica-based matrix.

The rejection is maintained, as are the rejections of claims 4 and 19-22 under 35 U.S.C. 103(a) over Smith et al. and Colpan, the rejection of claims 11-13 under 35 U.S.C. 103(a) over Smith et al. and the rejection of claim 15 under 35 U.S.C. 103(a) over Smith et al. and Heid et al.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
December 20, 2011